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PATRA L. PABST  
HOLLAND AND KNIGHT LLP  
1201 WEST PEACHTREE STREET, N.E.  
SUITE 2000, ONE ATLANTIC CENTER  
ATLANTA, GA 30309-3400

EXAMINER

MONSHIPOURI, MARYAM

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 05/01/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.



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Applicant's response to restriction requirement filed 3/28/01 (Paper #9) is acknowledged. Applicant elected Group I directed to claims 1-5 and SEQ ID NO:1 with traverse. Claims 6-13 and claims 1-5 drawn to SEQ ID NO:2 are withdrawn as drawn to non-elected inventions.

In traversal of restriction requirement applicant argues the following : (1) that rejoining inventions I-III does not impose an undue burden of searching on the examiner because the method of Group I can only be used to produce the compositions of Group II thus the claims should be examiner together.

(2) That claims 1-12 are generic and SEQ ID NO:1 should be considered as a species and that once claims directed to SEQ ID NO:1 become allowable additional species should be examined.

(3) Since the terminals of SEQ ID NO:1 and 2 are identical said sequences are related and thus are not patentably distinct.

These arguments were fully considered but were found unpersuasive. This is because with respect to applicant's **first** argument applicant is reminded that as mentioned previously, the method of Group I may produce many other animal feed additive products comprising phytases and phosphatases etc in addition to protease of this invention, that are entirely different products

**coextensive.** Applicant did not provide any arguments with regards to rejoining Group III

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invention with those of Groups I-II. Thus said invention remains distinct from others for the reasons of record.

With respect to applicant's **second** argument, it should be noted that the previous office action claims 1-13 were held as generic to two distinct inventions. The examiner did not mentioned any species whatsoever. SEQ ID NO:1-2 were referred to as patentably distinct inventions and not patentably distinct species. The examiner would like to express her apologies if said office action was not clear enough and would like to reword her restriction as following:

pending claims are directed to six patentably distinct invention as following:

- I(a) Claims 1-5, drawn to a method of animal feed preparation wherein said feed comprises acid resistant protease from *Nocardiopsis sp.* Set forth as SEQ ID NO:1, classified in class 435, subclass 220.
  - I(b) Claims 1-5, drawn to a method of animal feed preparation wherein said feed comprises acid resistant protease from *Nocardiopsis alba* set forth as SEQ ID NO:2, classified in class 435, subclass 220.
  - II(a) Claims 6-10 and 13, drawn to animal feed additives and animal feed compositions comprising SEQ ID NO:1, classified in class 426, subclass 656.
  - III(a) Claims 11-12, drawn to methods of treatment of vegetable proteins comprising adding
- SEQUENCE LISTING

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III(b) Claims 11-12, drawn to methods of treatment of vegetable proteins comprising adding SEQ ID NO:2 protease, classified in class 435, subclass 68.1.

Therefore claims 1-12 are not generic to patentably distinct species but are directed to **patentably distinct inventions** (see the previous office action, page 3).

With respect to applicant's **third** argument, the examiner disagrees that SEQ ID NO:1-2 are related because of their similarity at the amino terminal. Again as previously, SEQ ID NO:1 and 2 are isolated from two distinct sources namely: *Nocardiopsis* sp. and *Nocardiopsis alba*. have different overall structures and each function in different environments. The slight similarity between said products at the amino terminal is not sufficient to support the fact that they are related to each other.

In conclusion, due to reasons provided here, in addition to those of record the restriction is maintained according to previous office action and is hereby made **Final**.

#### **DETAILED ACTION**

**Claims 1-5 directed to SEQ ID NO:1 are under examination on the merits.** Claims 6-19 and claims 1-5 directed to SEQ ID NO:2 are withdrawn as drawn to non-elected inventions.

be a space between "the protease" and "has". Appropriate correction is required.

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2. Claims 3-4 are objected to because of the following informalities: the phrase "the use of claim 1 or claim 2" in claims 3 and 4 respectively, does not make sense. Applicant is advised to rewrite said phrase as "the method according to claim 1 or 2". Appropriate correction is required.

3. *Priority*

4. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

*Specification*

5. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

*Claim Rejections - 35 USC § 112*

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim s 1-5 provide for the use of acid-stable proteases, but, since the claim does not set

positive steps delimiting how this use is actually practiced.

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Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bedford et. Al. (WO 96/05739, Feb 1996, cited in the IDS) in view of Snow-Brand-Milk-Prod. patent ( JP 02255081, 1990, see abstract in English), from now on referred to as Snow-Brand. Bedford teaches methods of preparation of an animal feed containing an enzyme feed additive, wherein said feed additive comprises a xylanase, a protease and a beta-glucanase (see abstract and pages

2-10, 12-13, 15-16, 18-19, 21-22, 24-25, 27-28, 30-31, 33-34, 36-37, 39-40, 42-43, 45-46, 48-49, 51-52, 54-55, 57-58, 60-61, 63-64, 66-67, 69-70, 72-73, 75-76, 78-79, 81-82, 84-85, 87-88, 90-91, 93-94, 96-97, 99-100, 102-103, 105-106, 108-109, 111-112, 114-115, 117-118, 120-121, 123-124, 126-127, 129-130, 132-133, 135-136, 138-139, 141-142, 144-145, 147-148, 150-151, 153-154, 156-157, 159-160, 162-163, 165-166, 168-169, 171-172, 174-175, 177-178, 180-181, 183-184, 186-187, 189-190, 192-193, 195-196, 198-199, 201-202, 204-205, 207-208, 210-211, 213-214, 216-217, 219-220, 222-223, 225-226, 228-229, 231-232, 234-235, 237-238, 240-241, 243-244, 246-247, 249-250, 252-253, 255-256, 258-259, 261-262, 264-265, 267-268, 270-271, 273-274, 276-277, 279-280, 282-283, 285-286, 288-289, 291-292, 294-295, 297-298, 300-301, 303-304, 306-307, 309-310, 312-313, 315-316, 318-319, 321-322, 324-325, 327-328, 330-331, 333-334, 336-337, 339-340, 342-343, 345-346, 348-349, 351-352, 354-355, 357-358, 360-361, 363-364, 366-367, 369-370, 372-373, 375-376, 378-379, 381-382, 384-385, 387-388, 390-391, 393-394, 396-397, 399-400, 402-403, 405-406, 408-409, 411-412, 414-415, 417-418, 420-421, 423-424, 426-427, 429-430, 432-433, 435-436, 438-439, 441-442, 444-445, 447-448, 450-451, 453-454, 456-457, 459-460, 462-463, 465-466, 468-469, 471-472, 474-475, 477-478, 480-481, 483-484, 486-487, 489-490, 492-493, 495-496, 498-499, 501-502, 504-505, 507-508, 510-511, 513-514, 516-517, 519-520, 522-523, 525-526, 528-529, 531-532, 534-535, 537-538, 540-541, 543-544, 546-547, 549-550, 552-553, 555-556, 558-559, 561-562, 564-565, 567-568, 570-571, 573-574, 576-577, 579-580, 582-583, 585-586, 588-589, 591-592, 594-595, 597-598, 600-601, 603-604, 606-607, 609-610, 612-613, 615-616, 618-619, 621-622, 624-625, 627-628, 630-631, 633-634, 636-637, 639-640, 642-643, 645-646, 648-649, 651-652, 654-655, 657-658, 660-661, 663-664, 666-667, 669-670, 672-673, 675-676, 678-679, 681-682, 684-685, 687-688, 690-691, 693-694, 696-697, 699-700, 702-703, 705-706, 708-709, 711-712, 714-715, 717-718, 720-721, 723-724, 726-727, 729-730, 732-733, 735-736, 738-739, 741-742, 744-745, 747-748, 750-751, 753-754, 756-757, 759-760, 762-763, 765-766, 768-769, 771-772, 774-775, 777-778, 780-781, 783-784, 786-787, 789-790, 792-793, 795-796, 798-799, 801-802, 804-805, 807-808, 810-811, 813-814, 816-817, 819-820, 822-823, 825-826, 828-829, 831-832, 834-835, 837-838, 840-841, 843-844, 846-847, 849-850, 852-853, 855-856, 858-859, 861-862, 864-865, 867-868, 870-871, 873-874, 876-877, 879-880, 882-883, 885-886, 888-889, 891-892, 894-895, 897-898, 900-901, 903-904, 906-907, 909-910, 912-913, 915-916, 918-919, 921-922, 924-925, 927-928, 930-931, 933-934, 936-937, 939-940, 942-943, 945-946, 948-949, 951-952, 954-955, 957-958, 960-961, 963-964, 966-967, 969-970, 972-973, 975-976, 978-979, 981-982, 984-985, 987-988, 990-991, 993-994, 996-997, 999-1000).

Snow-Brand's patent teaches a thermostable alkaline protease from *Nocardiosis* sp.

(JP 02255081, 1990, see abstract in English), from now on referred to as Snow-Brand.

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21 Kilodalton and maintains residual activity of above 80% at pH 4-8. Since the enzyme source of Snow-Brand's patent is identical to the protease of this invention and pH/temperature-activity profile and molecular weight of Snow-Brand's protease is almost identical to SEQ ID NO:1 of this invention it is reasonable to assume that, its protease is at least 70% identical to SEQ ID NO:1 of this invention, even though Snow-Brand does not explicitly disclose an amino acid composition for its enzyme

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to start with the method of animal feed preparation of Bedford and replace its protease which is mainly stable and active at alkaline pH's with that from Snow-Brand's patent. One of ordinary skill in the art is motivated to replace the protease of Bedford with that from the snow-Brand patent because Snow-Brand's protease retains high levels of residual activity at acidic pH's and can act on the feed in animal stomach (acidic environment) longer than the Bacillus protease in order to release more feed protein and energy, thereby increasing its nutritional value, and rendering it more economical.

One of ordinary skill has a reasonable expectation of success in preparing feed comprising the protease including those from *Nocardopsis* sp. because methods of preparing animal feed


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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Maryam Monshipouri, Ph.D. whose telephone number is (703) 308- 1083.

The Examiner can normally be reached daily from 8:30 A.M. to 5:00 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. P. Achutamurthy, can be reached at (703) 308-3804. The OFFICIAL fax number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

  
Maryam Monshipouri, Ph.D.

Patent Examiner